

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Bruce G. Gold

**Application No.** Not yet assigned

**Filed:** March 19, 2004

**Confirmation No.** --

**For:** COMPOSITIONS AND METHODS FOR  
PROMOTING NERVE REGENERATION

**Examiner:** Not yet assigned

**Art Unit:** Not yet assigned

**Attorney Reference No.** 899-68196

MAIL STOP PATENT APPLICATION  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**FOR CONTINUING APPLICATIONS**

Listed on the accompanying form PTO-1449 are several English-language documents.

Applicant respectfully requests that such documents be listed as references cited on the issued patent.

The present application relies upon U.S. Patent Application No. 10/030,904, which was filed January 8, 2002, for an earlier filing date under 35 U.S.C. § 120. Furthermore, most documents listed on the accompanying form PTO-1449 were disclosed to or cited by the Patent Office in the earlier U.S. application.

If the present application was filed after June 30, 2003, copies of United States patents and United States published patent applications do not have to be provided to the Patent Office. This requirement of 37 C.F.R. § 1.98(a)(2)(i) has been waived by the United States Patent and

Trademark Office pursuant to the Official Gazette Notice on August 5, 2003 (1276 OG 55).

Applicant will provide copies of such patents upon request.

Copies of the documents listed on the accompanying form PTO-1449 that were cited by or submitted to the Patent Office in the earlier application need not be sent to the Patent Office pursuant to 37 C.F.R. § 1.98. However, applicant will furnish the Patent Office with such copies upon request. Several documents that were not previously submitted to the Patent Office in the earlier application are enclosed.

The filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By

  
\_\_\_\_\_  
Aden A. Rehms, Ph.D.  
Registration No. 55,935

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 226-7391  
Facsimile: (503) 228-9446

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Attorney Docket Number	899-68196
	Application Number	Not yet assigned
	Filing Date	
	First Named Inventor	Gold
	Art Unit	Not yet assigned
	Examiner Name	Not yet assigned

**U.S. PATENT DOCUMENTS**

NOTE: If this application was filed after June 30, 2003, copies of United States patents and United States published patent applications do not have to be provided to the Patent Office. This requirement of 37 C.F.R. § 1.98(a)(2)(i) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on August 5, 2003 (1276 OG 55).

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Pattee
		4,228,079	10.14.1980	Calton
		5,192,773	3.9.1993	Armistead et al.
		5,330,993	7.19.1994	Armistead et al.
		5,516,797	5.14.1996	Armistead et al.
		5,525,523	6.11.1996	Soldin
		5,543,423	8.6.1996	Zelle et al.
		5,612,350	3.18.1997	Or et al.
		5,614,547	3.25.1997	Hamilton et al.
		5,620,971	4.15.1997	Armistead et al.
		5,622,970	4.22.1997	Armistead et al.
		5,639,592	6.17.1997	Evans et al.
		5,650,430	7.22.1997	Sugimura et al.
		5,654,332	8.5.1997	Armistead
		5,780,484	7.14.1998	Zelle et al.
		5,811,434	9.22.1998	Zelle et al.
		5,840,736	11.24.1998	Zelle et al.

EXAMINER  
SIGNATURE:DATE  
CONSIDERED:

\* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Attorney Docket Number	899-68196
	Application Number	Not yet assigned
	Filing Date	
	First Named Inventor	Gold
	Art Unit	Not yet assigned
	Examiner Name	Not yet assigned

**U.S. PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		5,968,921	10.19.1999	Gold
		6,037,370	3.14.2000	Armistead

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		PCT	WO 92/04370	3.19.1992	
		PCT	WO 92/19593	11.12.1992	
		PCT	WO 92/19745	11.12.1992	
		PCT	WO 92/21313	12.10.1992	
		PCT	WO 93/07269	4.15.1993	
		PCT	WO 93/23548	11.25.1993	
		PCT	WO 96/25928	8.29.1996	Feng et al.
		PCT	WO 96/40140	12.19.1996	
		PCT	WO 96/40633	12.19.1996	
		PCT	WO 97/18828	5.29.1997	
		PCT	WO 98/20891	5.22.1998	
		PCT	WO 98/20892	5.22.1998	
		PCT	WO 98/20893	5.22.1998	

EXAMINER SIGNATURE:	DATE CONSIDERED:
---------------------	------------------

\* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	899-68196		
		Application Number	Not yet assigned		
		Filing Date			
		First Named Inventor	Gold		
		Art Unit	Not yet assigned		
		Examiner Name	Not yet assigned		
<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Pattee
		PCT	WO 98/30900	7.1998	Trier
		PCT	WO 99/21552	5.6.1999	
		PCT	WO 99/51223	10.14.1999	DeFranco et al.
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>			
		Armistead et al., "Design, Synthesis And Structure Of Non-Macrocyclic Inhibitors Of FKBP12, The Major Binding Protein For The Immunosuppressant FK506," <i>Acta Cryst Vol. D51</i> , pp. 522-528 (1995).			
		Bornfeldt et al., "Insulin-Like Growth Factor-I And Platelet-Derived Growth Factor-BB Induce Directed Migration Of Human Arterial Smooth Muscle Cell Via Signaling Pathways That Are District From Those Of Proliferation," <i>J Clin Invest.</i> , Vol. 93, pp. 1266-74, Abstract only (1994).			
		Bozzo et al., "Role Of Tyrosine Phosphorylation In Matrix-Induced Neurite Outgrowth In Human Neuroblastoma Cells," <i>Exp. Cell Res.</i> , Vol. 214, pp. 313-22 (1994).			
		Buttemeyer et al., "Peripheral Nerve Allograft Transplantation With FK 506: Functional, Histological, And Immunological Results Before And After Discontinuation of Immunosuppression," <i>Ann. Plast. Surg.</i> , Vol. 35, pp. 396-401 (1995).			
		Buttemeyer et al., "Peripheral Nerve Allotransplant Immunosuppressed With FK 506: Preliminary Results," <i>Transpl. Proc.</i> , Vol. 27, pp. 1877-1878 (1995).			
		Campbell V et al., "Biphasic Modulation Of Intracellular Ca <sup>2+</sup> -Concentration By Interleukin-1beta In Cortical Synaptosomes: Involvement Of A Pertussis Toxin-Sensitive G-Protein And Mitogen-Activated Protein Kinase," <i>Neuroreport.</i> , Vol. 9, pp. 1923-1927, Abstract only (1998).			
		Carney, et al., "A New Bastadin from the Sponge Psammaplysilla Purpurea," <i>J. of Natural Products</i> , Vol. 56, p. 153-157 (January 1993).			

EXAMINER  
SIGNATURE:DATE  
CONSIDERED:

\* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	899-68196
		Application Number	Not yet assigned
		Filing Date	
		First Named Inventor	Gold
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
		Chang, "Hyaluronidase Enhancement Of TNF-Mediated Cell Death Is Reversed By TGF-Beta 1," <i>Am J Physiol.</i> , Vol. 273, pp. C1987-C1994, Abstract only (1997).	
		Chao et al., "Differential Raf Requirement For Activation Of Mitogen-Activated Protein Kinase By Growth Factors, Phorbol Esters, And Calcumim," <i>J Biol Chem.</i> , Vol. 269, pp. 7337-7341, Abstract only (1994).	
		Chen et al., "Bastadin 10 Stabilized the Open Conformation of the Ryanodine-sesitive ca2+ Channel in an FKBP-12 Dependent Manner" abstract, <i>J. Biol. Chem.</i> , Vol. 274, p. 32603-32612 (1999).	
		Czar et al., "Geldanamycin, A Heat Shock Protein 90-Binding Benzoquinone Ansamycin, Inhibits Steroid-Dependent Translocation Of The Glucocorticoid Receptor From The Cytoplasm To The Nucleus," <i>Biochemistry</i> , Vol. 36, pp. 7776-7785 (1997).	
		David et al., "Anoxal Elongation Into Peripheral Nervous Systme "Bridges" After Central Nervous System Injury In Adult Rats," <i>Science</i> , Vol. 214, pp. 931-933 (1981).	
		DiJulio et al., "Ryanodine Receptor Type III (Ry3R) Identification In Mouse Parotid Acini. Properties And Modulation Of [3H] Ryanodine-Binding Sites," <i>J. Biol Chem.</i> , Vol. 272, pp. 15687-15696, Abstract only (1997).	
		Edwards et al., "Heat Shock Alters The Composition Of Heteromeric Steroids Receptor Complexes And Enhances Receptor Activity In Vivo." <i>Biochem.</i> , Vol. 31, pp. 2482-2491, Abstract only (1992).	
		Franklin et al., "Bastadin 20 and Bastadin o-Sulfate Esters from Ianthella Basta: Novel Modulators of the Ry1R FKBP12 Receptor Complex," <i>J. of Natural Products</i> , Vol. 59, p. 1121-1127 (1996).	
		Frodin et al., "Glucose, Other Secretagogues, And Nerve Growth Factor Stimulate Mitogen-Activated Protein Kinase In The Insulin-Secreting Beta-Cell Line, INS-1," <i>J Biol Chem.</i> , Vol. 270, pp. 7882-7889, Abstract only (1995).	
		Gold, "FK506 and the Role of the Immunophilin FKBP-52 in Nerve Regeneration," <i>Drug Metabolism Reviews</i> , Vol. 31, No. 3, pp. 649-663 (1999).	
		Gulavita et al., "Isolation and Structure Elucidation of 34-Sulfatobastadin 13, An Inhibitor of the Endothelin a Receptor, from a Marine Sponge of the Genus Ianthella," <i>J. of Natural Products</i> , Vol. 56, p. 1613-1617 (September 1993).	

EXAMINER SIGNATURE:	DATE CONSIDERED:
------------------------	---------------------

\* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	899-68196
		Application Number	Not yet assigned
		Filing Date	
		First Named Inventor	Gold
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
		Pahan et al., "Sphingomyelinase And Ceramide Stimulate The Expression Of Inducible Nitric-Oxide Synthase In Rat Primary Astrocytes," <i>J. Biol Chem.</i> , Vol. 273, pp. 2591-2600, Abstract only (1998).	
		Pessah et al., "Bastadins Relate Ryanodine-Sensitive And -Insensitive Ca <sup>2+</sup> Efflux Pathways In Skeletal SR And BC3H1 Cells," <i>Am J Physiol.</i> , Vol. 272, pp. C601-614, Abstract only (1997).	
		Pettit et al., "Antineoplastic Agents, 326. The Stereochemistry of Bastadins 8, 10, and 12 from the Bismarck Archipelago Marine Sponge Iantehella Basta," <i>J. of Natural Products</i> , Vol. 58, p. 680-688 (May 1995).	
		Pratt et al., "Steroid Receptor Interactions With Heat Shock Protein And Immunophilin Chaperones," <i>Endocrine Reviews</i> , Vol. 18, pp. 306-360 (1997).	
		Pratt, "The hsp90-based Chaperone System: Involvement in Signal Transduction from a Variety of Hormone and Growth Factor Receptors," <i>Hsp90 and Signal Transduction</i> , pp. 420-434 (1998).	
		Pratt, "The Role Of The hsp90-Based Chaperone System In Signal Transduction By Nuclear Receptors And Receptors Signaling Via MAP Kinase," <i>Annu. Rev. Pharmacol. Toxicol.</i> , Vol. 37, pp. 297-326 (1997).	
		Preis et al., "Neuronal Cell Differentiation Of Human Neuroblastoma Cells By Retinoic Acid Plus Herbimycin A," <i>Cancer Res.</i> , Vol. 48, pp. 6530-6534 (1988).	
		Ratajczak et al., "Cyclophilin 40 (CyP-40), Mapping Of Its hsp90 Binding Domain And Evidence That FKBP52 Competes With CyP-40 For hsp90 Binding," <i>J. Biol. Chem.</i> , Vol. 271, pp. 2961-2965 (1996).	
		Samanta et al., "Hydrogen Peroxide Enhances Signal-Responsive Arachidonic Acid Release From Neurons: Role of Mitogen-Activated Protein Kinase," <i>J Neurochem.</i> , Vol. 70, pp. 2082-2090, Abstract only (1998).	
		Sanchez et al., "Immunophilins, Heat Shock Proteins, And Glucocorticoid Receptor Actions <i>In Vivo</i> ," <i>Methods</i> , Vol. 9, pp. 188-200 (1996).	
		Sano et al., "Radicicol Potentiates Neurotrophin-mediated Neurite Outgrowth and Survival of Cultured Sensory Neurons from Chick Embryo," <i>J. of Neurochemistry</i> , Vol. 72, pp. 2256-2263 (1999).	

EXAMINER SIGNATURE:	DATE CONSIDERED:
* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	899-68196
		Application Number	Not yet assigned
		Filing Date	
		First Named Inventor	Gold
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
		Schliess et al., "Mitogen-Activated Protein Kinases Mediate The Stimulation Of Bile Acid Secretion By Tauroursodeoxycholate In Rat Liver," <i>Gastroenterology</i> , Vol. 113, pp. 1306-1314, Abstract only (1997).	
		Schulte et al., "Antibiotic Radicicol Binds to the N-terminal Domain of Hsp90 and Shares Important Biologic Activities With Geldanamycin," <i>Cell Stress &amp; Chaperones</i> , Vol. 3, p. (1996).	
		Segnitz et al., "The Function Of Steroid Hormone Receptors Is Inhibited By The hsp90-Specific Compound Geldanamycin," <i>J. Biol. Chem.</i> , Vol. 272, pp. 18694-18701 (1997).	
		Sherwood et al., "Differential Regulation Of MAP Kinase, p70(S6K), And Akt By Contraction And Insulin In Rat Skeletal Muscle," <i>Am J Physiol.</i> , Vol. 276, pp. E870-E878, Abstract only (1999).	
		Shimada et al., "Induction Of Differentiation Of HL-60 Cells By The Anti-Fungal Antibiotic, Radicicol," <i>J Antibiot (Tokyo)</i> , Vol. 48, pp. 824-830, Abstract only (1995).	
		Smith, "Dynamics Of Heat Shock Protein 90-Progesterone Receptor Binding And The Disactivation Loop Model For Steroid Receptor," <i>Mol. Endocrinol.</i> , Vol. 7, pp. 1418-1429, Abstract only (1993).	
		Smith, "Elements Of Molecular Neurobiology," 2 <sup>nd</sup> ed., John Wiley & Sons, pp. 141-142 (1996).	
		Smith et al., "Progesterone Receptor Structure And Function Altered By Geldanamycin, An hsp90-Binding Agent," <i>Molecular and Cellular Biology</i> , Vol. 15, pp. 6804-6812 (1995).	
		Stancato et al., "The hsp90-binding Antibiotic Geldanamycin Decreases Raf Levels And Epidermal Growth Factor Signaling Without Disrupting Formation Of Signaling Complexes Or Reducing The Specific Enzymatic Activity Of Raf Kinase," <i>J. Biol. Chem.</i> , Vol. 272, pp. 4013-4020 (1997).	
		Stebbins et al., "Crystal Structure Of An Hsp90-Geldanamycin Complex: Targeting Of A Protein Chaperone By An Antitumor Agent," <i>Cell</i> , Vol. 89, pp. 239-250 (1997).	
		Tanzer et al., "Gonadal Steroid Regulation Of Hamster Facial Nerve Regulation: Effects Of Dihydrotestosterone And Estradiol," <i>Exp. Neurol.</i> , Vol. 146, pp. 258-264 (1997).	

EXAMINER SIGNATURE:	DATE CONSIDERED:
* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	899-68196
		Application Number	Not yet assigned
		Filing Date	
		First Named Inventor	Gold
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
		Tomono et al., "Inhibitors Of Calcineurin Block Expression Of Cyclins A And E Induced By Fibroblast Growth Factor In Swiss 3T3 Fibroblasts," <i>Arch Biochem Biophys.</i> , Vol. 353, pp. 374-378, Abstract only (1998).	
		Tsuchiya et al., "Expression Of Leptin Receptor In Lung: Leptin As A Growth Factor," <i>Eur J. Pharmacol.</i> , Vol. 365, pp. 273-279, Abstract only (1999).	
		Tumlin et al., "Aldosterone And Dexamethasone Stimulate Calcineurin Activity Through A Transcription-Independent Mechanism Involving Steroid Receptor-Associated Heat Shock Proteins," <i>J. Clin. Investigation</i> , Vol. 99, pp. 1217-1223, Abstract only (1997).	
		Weiss et al., "MEK Inhibition Augments Raf Activity, But Has Variable Effects On Mitogenesis, In Vascular Smooth Muscle Cells," <i>Am J Physiol.</i> , Vol. 274, pp. C1521-C1529, Abstract only (1998).	
		Wells et al., "Gel Matrix Vehicles For Growth Factor Application In Nerve Gap Injuries Repaired With Tubes: A Comparison Of Biomatrix, Collagen, And Methylcellulose," <i>Exp. Neurol.</i> , Vol. 146, pp. 395-402 (1997).	
		Whitesell et al., "Benzoquinonoid Ansamycins Possess Selective Tumoricidal Activity Unrelated To src Kinase Inhibition," <i>Cancer Res.</i> , Vol. 52, pp. 1721-1728 (1992).	
		Whitesell et al., "Inhibition Of Heat Shock Protein HSP90-pp60 <sup>v-src</sup> Heteroprotein Complex Formation By Benzoquinone Ansamycins: Essential Role For Stress Proteins in Oncogenic Transformation," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91, pp. 8324-8328 (1994).	

EXAMINER SIGNATURE:	DATE CONSIDERED:
* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	899-68196
		Application Number	Not yet assigned
		Filing Date	
		First Named Inventor	Gold
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
		Itoh et al., "A Protein Factor For Ras p21-Dependent Activation Of Mitogen-Activated Protein (MAP) Kinase Through MAP Kinase Kinase," <i>Proc Natl Acad Sci U.S.A.</i> , Vol. 90, pp. 975-979, Abstract only (1993).	
		Jackowski, "Neural Injury Repair: Hope For The Future As Barriers To Effective CNS Regeneration Become Clearer," <i>Brit. J. Neurosurg.</i> , Vol. 9, pp. 303-317 (1995).	
		Kato et al., "BMK1/ERK5 Regulates Serum-Induced Early Gene Expression Through Transcription Factor MEF2C," <i>EMBO J.</i> , Vol. 16, pp. 7054-7066, Abstract only (1997).	
		Kuhn et al., "Progesterone-Binding Components Of Chick Oviduct. Biochemical Characterization Of Purified Oviduct Progesterone Receptor B Subunit," <i>J. Biol. Chem.</i> , Vol. 252, pp. 308-317, Abstract only (1977).	
		Kwon et al., "Potent And Specific Inhibition Of p60v-src Protein Kinase Both In Vivo And In Vitro By Radicicol," <i>Cancer Res.</i> , Vol. 52, pp. 6926-6930, Abstract only (1992).	
		Mack et al., "Novel Modulators of Skeletal Muscle FKBP12/Calcium Channel Complex from Ianthella Basta. Role of FKBP12 in Channel Gating" abstract, <i>J. Biol. Chem.</i> , Vol. 269, p. 23236-23249 (1994).	
		Miao et al., "Cytotoxic Metabolites from the Sponge Ianthella Basta Collected in Papua New Guinea," <i>J. of Natural Products</i> , Vol. 33, p. 1441-1446 (Nov.-Dec. 1990).	
		Miller et al., "Increased Neurite Outgrowth Induced By Inhibition Of Protein Tyrosine Kinase Activity In PC12 Pheochromocytoma Cells," <i>J. Neurochem.</i> , Vol. 60, pp. 2134-2144 (1993).	
		Ohtsuki et al., "Delayed Neuronal Death in Ischemic Hippocampus Involves Stimulation of Protein Tyrosine Phosphorylation," <i>American J. of Physiology</i> , Vol. 271(4), p. C1085-C1097 (1996).	
		Owens-Grillo et al., "Binding Of Immunophilins To The 90 kDa Heat Shock Protein (hsp90) Via A Tetratricopeptide Repeat Domain Is A Conserved Protein Interaction In Plants," <i>Biochemistry</i> , Vol. 35, pp. 15249-15255 (1996).	
		Owens-Grillo et al., "The Cyclosporin A-binding Immunophilin CyP-40 And The FK506-Binding Immunophilin hsp56 Bind To A Common Site On hsp90 And Exist In Independent Cytosolic Heterocomplexes With The Untransformed Glucocorticoid Receptor," <i>J. Biol. Chem.</i> , Vol. 270, pp. 20479-20484 (1995).	

EXAMINER SIGNATURE:	DATE CONSIDERED:
---------------------	------------------

\* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.